

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD.,
Plaintiff,

V.

SAREPTA THERAPEUTICS, INC.,
Defendant.

C.A. No. 21-1015 (GBW)

DEMAND FOR JURY TRIAL

SAREPTA THERAPEUTICS, INC. and THE
UNIVERSITY OF WESTERN AUSTRALIA,
Defendant/Counter-Plaintiffs

V.

NIPPON SHINYAKU CO., LTD. and NS
PHARMA, INC.,
Plaintiff/Counter Defendants.

**PLAINTIFF’S CONCISE STATEMENT OF FACTS IN SUPPORT OF ITS MOTION
FOR PARTIAL SUMMARY JUDGMENT NO. 3 REGARDING
ITS BREACH OF CONTRACT CLAIM**

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Defendant NS Pharma, Inc.*

Dated: December 11, 2023

I. AGREEMENT BETWEEN NS AND SAREPTA

1. On June 1, 2020, Nippon Shinyaku Co., Ltd. (“NS”) and Sarepta Therapeutics, Inc. (“Sarepta”) executed a Mutual Confidentiality Agreement (“MCA”), effective June 1, 2020. *See* Compl., Ex. A (D.I. 2-1); Sarepta’s Second Am. Answer (D.I. 328), ¶¶ 1, 61.

2. The MCA is a valid and enforceable contract. *See* Sarepta’s Countercls. (D.I. 328), ¶ 87.

3. In addition to confidentiality provisions, the MCA includes a covenant not to sue for the term of the agreement and a forum selection clause governing where the parties can bring patent infringement and invalidity challenges for two years after the MCA expired. *See* Compl., Ex. A (D.I. 2-1); NS’s Second Am. Compl. (D.I. 86), ¶¶ 62, 63; Sarepta’s Second Am. Answer (D.I. 328), ¶¶ 62, 63.

4. During the Covenant Term¹, which the parties agree expired on June 21, 2021, (Sarepta Opp’n to Mot. for P.I. (D.I. 18) at 1), the MCA provides a “Covenant Not to Sue or Initiate a Patent Challenge” that states, in relevant part:

[E]ach Party . . . hereby covenants and irrevocably agrees that **during the Covenant Term it shall not directly or indirectly assert or file any legal or equitable cause of action, suit or claim or otherwise initiate any litigation or other form of legal or administrative proceeding against the other Party**, its Affiliates, licensors or licensees thereof, other than an action, suit or claim that is statutorily barred from being filed if not filed during the Covenant Term in any jurisdiction in the United States or Japan of or concerning intellectual property in the field of [DMD]. For clarity, **this covenant not to sue includes**, but is not limited to, patent infringement litigations, declaratory judgment actions, **patent validity challenges before the U.S. Patent and Trademark Office** or Japanese Patent Office, and reexamination proceedings before the U.S. Patent and

¹ The MCA defines “Covenant Term” as “the time period commencing on the Effective Date and ending upon twenty (20) days after the earlier of: (i) expiration of the Term, or (ii) the effective date of termination.” Compl., Ex. A at 2; Sarepta Opp’n to Mot. for P.I. (D.I. 18) at 1. The “Effective Date” is defined as June 1, 2020. Compl., Ex. A at 2. The “Term” is defined as “a period of one (1) year following the Effective Date.” *Id.* at 6, § 7; NS’s Second Am. Complaint (D.I. 86), ¶ 65; Sarepta’s Second Am. Answer (D.I. 328), ¶ 65.

Trademark Office involving patents controlled or Controlled by a Party or its Affiliates of or concerning treatments for [DMD]. . . . For further clarity, **this covenant not to sue applies only to Potential Actions in the United States and Japan.**

Compl., Ex. A, § 6.1; NS's Second Am. Compl. (D.I. 83), ¶ 62; Sarepta's Second Am. Answer (D.I. 328), ¶ 62.²

5. The MCA also includes a forum selection clause titled "Governing Law; Jurisdiction; Attorney's Fees" that states in relevant part:

This Agreement and all actions thereto shall be governed by and interpreted in accordance with the laws of the State of Delaware, United States of America, without giving effect to any conflict of laws provisions.

* * *

. . . the Parties agree that **all Potential Actions arising under U.S. law relating to patent infringement or invalidity, and filed within two (2) years of the end of the Covenant Term, shall be filed in the United States District Court for the District of Delaware** and that neither Party will contest personal jurisdiction or venue in the District of Delaware and that neither Party will seek to transfer the Potential Actions on the ground of *forum non conveniens*.

Compl., Ex. A, § 10; NS's Second Am. Compl. (D.I. 86), ¶ 69; Sarepta's Second Am. Answer (D.I. 328), ¶ 69.

6. This forum selection clause thus provides that for two years following the end of the Covenant Term (*i.e.*, two years after June 21, 2021), all "Potential Actions" arising under U.S. law relating to patent infringement and invalidity shall be filed in the United States Court for the District of Delaware. The parties defined the term "Potential Actions" as follows:

[A]ny patent or other intellectual property disputes between NS and Sarepta, or their Affiliates, other than the EP Oppositions or JP Actions, **filed with a court or administrative agency prior to or after the Effective Date in the United States**, Europe, Japan or other countries in connection with the Parties' development and commercialization of therapies for Duchenne Muscular Dystrophy.

² All emphasis added unless otherwise stated.

Compl., Ex. A at 2; NS’s Second Am. Compl. (D.I. 86), ¶ 70; Sarepta’s Second Am. Answer (D.I. 328), ¶ 70.

7. This forum selection clause is unambiguous on its face. Fed. Cir. Op. (D.I. 92-1) at 10.

II. SAREPTA FILES IPR PETITIONS CHALLENGING THE VALIDITY OF THE NS PATENTS.

8. On June 21, 2021, Sarepta filed seven *inter partes* review petitions (“IPR Petitions”) before the Patent Trial and Appeal Board challenging the validity of U.S. Patent Nos. 9,708,361; 10,385,092; 10,407,461; 10,487,106; 10,647,741; 10,662,217; and 10,683,322 (collectively, the “NS Patents”). Sarepta’s Second Am. Answer (D.I. 328), ¶ 1.

9. NS filed a Motion for Preliminary Injunction in this Court seeking to enjoin the IPR Petitions. D.I. 4.

III. THE FEDERAL CIRCUIT MANDATES ENTRY OF INJUNCTION AND DETERMINES IPR PETITIONS WERE FILED IMPROPERLY

10. After the District Court denied NS’s Motion for Preliminary Injunction, the Federal Circuit reversed and ordered that the District Court enter a preliminary injunction. Fed. Cir. Op. (D.I. 92-1) at 16.

11. The Federal Circuit held that “[u]nder the plain language of Section 10 [of the MCA], Sarepta was required to bring all disputes regarding the invalidity of [NS’s] patents—including the allegations and contentions contained in Sarepta’s IPR petitions—in the District of Delaware.” *Id.* at 10. The Federal Circuit went on to hold that Sarepta’s bringing “those disputes in the form of IPR Petitions at the [PTAB] . . . contravened the plain language of the forum selection clause in Section 10 of the MCA.” *Id.* Thus, the Federal Circuit “conclude[ed] as a matter of law that the forum selection clause in Section 10 of the MCA precludes the filing of IPR

petitions during the two-year period following the expiration of the Covenant Term on June 21, 2021” and that Sarepta had violated this provision of the MCA. *Id.* at 14.

IV. NS [REDACTED] SAREPTA’S DAMAGES FIGURE FOR THE BREACH OF CONTRACT CLAIM

12. NS has incurred at least \$ [REDACTED] in attorneys’ fees and costs pursuing its breach of contract claim against Sarepta, and at least \$ [REDACTED] in connection with its legal fees for opposing Sarepta’s IPR Petitions regarding the NS Patents. *See* Ex. 21 (App. to First Suppl. Rog. 21 Resp.); Ex. 10 (Excerpts of Rebuttal Expert Report of John C. Jarosz (“Jarosz Rebuttal”)), ¶¶ 198, 320.

13. On October 11, 2023, Sarepta served the Jarosz Rebuttal in which Mr. Jarosz opined that the total damages incurred in the IP Litigation was no more than \$ [REDACTED] and in PTAB-related damages was no more than \$ [REDACTED], for a total of no more than \$ [REDACTED] in damages related to Sarepta’s alleged breach of the MCA. *See* Ex. 10 (Jarosz Rebuttal), ¶¶ 198, 320.

14. For purposes of its Motion for Summary Judgment only, NS [REDACTED]
[REDACTED].³ *See* Brief Filed Contemporaneously Herewith ([REDACTED]).

³ Insofar as the Court does not grant summary judgment in favor of NS regarding its breach of contract claim, NS reserves all rights to assert that it is entitled to a different (and higher) damages number at trial as explained more fully in its damages expert report.